Collegium Completes Acquisition of Ironshore Therapeutics

September 4, 2024

– Adds Commercial Product Jornay PM®, Establishing Collegium's Presence in Neurology (ADHD) –

– Collegium Updates 2024 Financial Guidance to Reflect Expected Immediate Accretion from the Ironshore Acquisition –

– 2024 Product Revenues, Net Expected in the Range of $620.0 Million to $635.0 Million –

STOUGHTON, Mass., Sept. 04, 2024 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions, today announced that it has completed the acquisition of Ironshore Therapeutics Inc., a privately held company that markets and distributes Jornay PM (methylphenidate HCl), a central nervous system (CNS) stimulant for the treatment of attention deficit hyperactivity disorder (ADHD). Collegium also updated its 2024 financial guidance to include the anticipated impact of the Ironshore acquisition.

"We are pleased to have successfully closed the acquisition of Ironshore, which represents an important milestone as we build a leading, diversified specialty pharmaceutical company," said Michael Heffernan, Chairman and Interim President and Chief Executive Officer of Collegium. "With the addition of Jornay PM to our portfolio, we are establishing our presence in the large and growing ADHD market with a highly differentiated product that is poised to become our leading growth driver. By leveraging our core commercial competencies and proven track record of efficiently and successfully integrating commercial products, we are well positioned to maximize our pain portfolio, seamlessly integrate Jornay PM, and the Ironshore team, into our business and deliver on the immediate accretion to both our top- and bottom-lines."

Strategic Rationale

- Strategically aligns with Collegium's mission of building a leading, diversified specialty pharmaceutical company by broadening the commercial portfolio beyond pain management and establishing a commercial presence in neurology via the large and growing ADHD market.
- Jornay PM is poised to become Collegium's leading growth driver. Net revenue for Jornay PM is expected to be in excess of $100 million in 2024. In the first half of 2024, Jornay PM prescriptions grew 32% year-over-year. For the full-year 2023, the product generated approximately 490,000 prescriptions, a 58% increase compared to 2022. Jornay PM is a highly differentiated treatment for ADHD due to its evening dosing, smooth therapeutic effect and dose-dependent duration.
- Jornay PM is supported by 16 Orange Book-listed patents, with expiries in 2032.
- Further strengthens Collegium's financial position through an increased revenue base, expected immediate accretion to adjusted EBITDA and accelerated cash flow generation.

For additional background on the acquisition, please read the announcement press release here and view Collegium's investor presentation here.

Additional Transaction Details

Under the terms of the agreement, Collegium acquired all the outstanding shares of Ironshore for $525 million in cash, which was funded by $200 million of Collegium's existing cash on hand and $325 million of Collegium's $646 million term loan provided by investment funds managed by Pharmakon Advisors, LP. Collegium will also pay Ironshore shareholders $25 million in additional consideration if Jornay PM net revenue exceeds a defined threshold in 2025. The balance of the $646 million five-year term loan was used to repay Collegium's prior $320.8 million term loan, reducing Collegium's interest rate by 300 basis points.

Financial Guidance for 2024

Collegium updates its full-year 2024 financial guidance for Product Revenues, Net, Adjusted Operating Expenses and Adjusted EBITDA, which includes four months of anticipated impact from the acquisition of Ironshore.

	Prior	Updated
Product Revenues, Net	$580.0 to $595.0 million	$620.0 to $635.0 million
Adjusted Operating Expenses (Excluding Stock-Based Compensation)	$120.0 to $125.0 million	$150.0 to $155.0 million
Adjusted EBITDA (Excluding Stock-Based Compensation)	$380.0 to $395.0 million	$395.0 to $405.0 million

About JORNAY PM®

JORNAY PM (methylphenidate HCl extended-release capsules) is a central nervous system (CNS) stimulant indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: ABUSE, MISUSE, AND ADDICTION

See full prescribing information for complete boxed warning.

- JORNAY PM has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including JORNAY PM, can result in overdose and death, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.
- Before prescribing JORNAY PM, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout JORNAY PM treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse and addiction.

See additional important safety information below.

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or other components of JORNAY PM. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate products.
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days because of the risk of hypertensive crisis.

WARNINGS AND PRECAUTIONS

JORNAY PM can cause serious adverse reactions and patients should be monitored for the following:

- *Risks to Patients with Serious Cardiac Disease:* Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.
- *Increased Blood Pressure and Heart Rate.*
- *Psychiatric Adverse Reactions:* Including exacerbation of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder, induction of a manic episode in patients with bipolar disorder, and new psychotic or manic symptoms. Prior to initiating treatment, screen patients for risk factors for psychiatric adverse reactions. If such symptoms occur, consider discontinuing JORNAY PM.
- *Priapism:* Patients should seek immediate medical attention.
- *Peripheral Vasculopathy, including Raynaud's Phenomenon:* Observe patients for digital changes during treatment.
- *Weight Loss and Long-Term Suppression of Growth in Pediatric Patients:* Monitor height and weight.
- *Increased Intraocular Pressure (IOP) and Glaucoma:* Patients at risk for acute angle closure glaucoma should be evaluated by an ophthalmologist. Closely monitor patients with a history of abnormally increased IOP or open angle glaucoma.
- *Onset or Exacerbation of Motor and Verbal Tics, and Worsening of Tourette's Syndrome.*

ADVERSE REACTIONS

- The most common (≥5% and twice the rate of placebo) adverse reactions with methylphenidate are decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, decreased weight, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure.
- Additional adverse reactions (≥5% and twice the rate of placebo) in JORNAY PM-treated pediatric patients 6 to 12 years are headache, psychomotor hyperactivity, and mood swings.

DRUG INTERACTIONS

- Antihypertensive drugs: Monitor blood pressure data. Adjust dosage of antihypertensive drug as needed.

To report SUSPECTED ADVERSE REACTIONS, contact Ironshore Pharmaceuticals Inc. at 1-877-938-4766 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please visit https://ironshorepharma.com/jornay-pm-label for additional important safety information and the Full Prescribing Information, including Boxed Warning, for JORNAY PM.

About Collegium Pharmaceutical, Inc.

Collegium is a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. Collegium's headquarters are located in Stoughton, Massachusetts. For more information, please visit Collegium's website at www.collegiumpharma.com.

Non-GAAP Financial Measures

We have included information about certain non-GAAP financial measures in this press release. We use these non-GAAP financial measures to understand, manage and evaluate our business as we believe they provide additional information on the performance of our business. We believe the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, provide analysts, investors, lenders, and other third parties with insights into how we evaluate normal operational activities, including our ability to generate cash from operations, on a comparable year-over-year basis and manage our budgeting and forecasting. In addition, certain non-GAAP financial measures, primarily Adjusted EBITDA, are used to measure performance when determining components of annual compensation for substantially all non-sales force employees, including senior management.

In this press release we discuss the following financial measures that are not calculated in accordance with GAAP.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income or loss adjusted to exclude interest expense, interest income, the benefit from or provision for income taxes, depreciation, amortization, stock-based compensation, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations. Adjusted EBITDA, as used by us, may be calculated differently from, and therefore

may not be comparable to, similarly titled measures used by other companies.

There are several limitations related to the use of adjusted EBITDA rather than net income or loss, which is the nearest GAAP equivalent, such as:

- adjusted EBITDA excludes depreciation and amortization, and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- adjusted EBITDA does not reflect changes in, or cash requirements for, working capital needs;
- adjusted EBITDA does not reflect the benefit from or provision for income taxes or the cash requirements to pay taxes;
- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments;
- we exclude stock-based compensation expense from adjusted EBITDA although: (i) it has been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy; and (ii) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary expense included in operating expenses would be higher, which would affect our cash position;
- we exclude impairment expenses from adjusted EBITDA and, although these are non-cash expenses, the asset(s) being impaired may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude restructuring expenses from adjusted EBITDA. Restructuring expenses primarily include employee severance and contract termination costs that are not related to acquisitions. The amount and/or frequency of these restructuring expenses are not part of our underlying business;
- we exclude litigation settlements from adjusted EBITDA, as well as any applicable income items or credit adjustments due to subsequent changes in estimates. This does not include our legal fees to defend claims, which are expensed as incurred;
- we exclude acquisition related expenses as the amount and/or frequency of these expenses are not part of our underlying business. Acquisition related expenses include transaction costs, which primarily consisted of financial advisory, banking, legal, and regulatory fees, and other consulting fees, incurred to complete the acquisition, employee-related expenses (severance cost and benefits) for terminated employees after the acquisition, and miscellaneous other acquisition related expenses incurred;
- we exclude recognition of the step-up basis in inventory from acquisitions (i.e., the adjustment to record inventory from historic cost to fair value at acquisition) as the adjustment does not reflect the ongoing expense associated with sale of our products as part of our underlying business;
- we exclude losses on extinguishments of debt as these expenses are episodic in nature and do not directly correlate to the cost of operating our business on an ongoing basis; and
- we exclude other expenses, from time to time, that are episodic in nature and do not directly correlate to the cost of operating our business on an ongoing basis.

Adjusted Operating Expenses

Adjusted operating expenses is a non-GAAP financial measure that represents GAAP operating expenses adjusted to exclude stock-based compensation expense, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations.

We have not provided a reconciliation of our full-year 2024 guidance for adjusted EBITDA or adjusted operating expenses to the most directly comparable forward-looking GAAP measures, in reliance on the unreasonable efforts exception provided under Item 10(e)(1)(i)(B) of Regulation S-K, because we are unable to predict, without unreasonable efforts, the timing and amount of items that would be included in such a reconciliation, including, but not limited to, stock-based compensation expense, acquisition related expense and litigation settlements. These items are uncertain and depend on various factors that are outside of our control or cannot be reasonably predicted. While we are unable to address the probable significance of these items, they could have a material impact on GAAP net income and operating expenses for the guidance period. A reconciliation of adjusted EBITDA or adjusted operating expenses would imply a degree of precision and certainty as to these future items that does not exist and could be confusing to investors.

Collegium Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "forecasts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements related to the anticipated benefits of the acquisition of Ironshore Therapeutics, the anticipated financial impact of the acquisition of Ironshore Therapeutics, our expectations for Jornay PM revenues, our full-year 2024 financial guidance, including projected product revenue, adjusted operating expenses and adjusted EBITDA, current and future market opportunities for our products and our assumptions related thereto, expectations (financial or otherwise) and intentions, and other statements that are not historical facts. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results, performance, or achievements to differ materially from Collegium's current expectations, including risks relating to, among others: risks related to our ability to realize the anticipated benefits of the acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully; disruption from the transaction making it more difficult to maintain business and operational relationships; negative effects of the consummation of the acquisition on the market price of our common stock and/or operating results; risks related to significant transaction costs or the acquisition of unknown liabilities; risks related to future opportunities and plans for Ironshore Therapeutics and Jornay PM, including uncertainty of the expected financial performance of Jornay PM; risks related to future opportunities and plans for our products, including uncertainty of the expected financial performance of such products; our ability to commercialize and grow sales of our products; our ability to manage our relationships with licensors; the success of competing products that are or become available; our ability to maintain regulatory approval of our products, and any related restrictions, limitations, and/or warnings in the label of our products; the size of the markets for our products, and our ability to service those markets; our ability to obtain reimbursement and third-party payor contracts for our products; the rate and degree of market acceptance of our products; the costs of commercialization activities, including marketing, sales and distribution; changing market conditions for our products; the outcome of any patent infringement or other litigation that may be brought by or against us; the outcome of any governmental investigation related to our business; our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and manufacture adequate supplies of commercially saleable inventory; our ability to obtain funding for our operations and business development; regulatory developments in the U.S.; our expectations regarding our ability to obtain and maintain sufficient intellectual property protection for our products; our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency (DEA) compliance; our customer concentration; and the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing. These and other risks are described under the heading "Risk Factors" in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other filings with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Investor Contact:
Christopher James, M.D.

Vice President, Investor Relations
ir@collegiumpharma.com

Media Contact:
Marissa Samuels
Vice President, Corporate Communications
communications@collegiumpharma.com

Source: Collegium Pharmaceutical, Inc.